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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,297	08/24/2005	Jonas Angstrom	0933-0232PUS1	6676

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EXAMINER	
BLAND, LAYLA D	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
09/25/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/518,297	ANGSTROM ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76-92 and 94-106* is/are pending in the application.

4a) Of the above claim(s) *76-91 and 98-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *92,94-97,105 and 106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/27/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is a response to Applicant's amendment submitted June 27, 2008, wherein claims 92 and 97 are amended, claim 93 is canceled, and new claims 105 and 106 are added.

Claims 76-106 are pending in this application. Claims 76-91 and 98-104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 5, 2007.

Claims 92, 94-97, 105, and 106 are examined on the merits herein.

In view of the cancellation of claim 93, all rejections made with respect to that claim in the previous office action are withdrawn.

In view of Applicant's amendment submitted June 27, 2008, the rejection of claim 92 and dependent claims under 35 USC 112, second paragraph, as being incomplete for omitting essential elements, is withdrawn.

The following new or modified rejections were necessitated by Applicant's amendment submitted June 27, 2008, wherein "gastrointestinal" was added and "bacterial" was removed from the claim language, significantly changing the scope of the claims, and wherein new claims 105 and 106 were added, and by submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on June 27, 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 92, 94-97, 105, and 106 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of gastrointestinal bacterial infections caused by *E. coli* and *zHelicobacter*, does not reasonably provide enablement for the prevention of any gastrointestinal infections, does not provide enablement for the treatment of gastrointestinal bacterial infections caused by other than *E. coli* and *zHelicobacter,* and does not provide enablement for the treatment of gastrointestinal viral or other parasitic infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination,

but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method of treatment for a gastrointestinal infection, wherein a pharmaceutically or therapeutically or prophylactically effective amount of a composition is administered to a subject in need. Thus, the claims taken together with the specification imply that any gastrointestinal infections can be treated or prevented (based on prophylactically effective amount) by administering the composition as described in claim 92.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Miller-Podraza et al. (WO 02/056893, July 25, 2002, PTO-1449 submitted December 17, 2004) teach the use of oligosaccharides for the treatment of conditions due to *Helicobacter pylori* [see abstract]. Vanmaele et al. (WO 00/51644, September 8, 2000, PTO-1449 submitted December 17, 2004) teach the use of oligosaccharides for the treatment of conditions mediated by *E. coli* [see abstract]. Prieto et al. (US 6,045,854, of record) teach that oligosaccharides protect infants from bacterial

infections of the respiratory, gastrointestinal, and urogenital tracts [column 1, lines 62-64].

Beachey (The Journal of Infectious Diseases, Vol. 143, No. 3, March 1981, pages 325-345, PTO-1449 submitted may 27, 2008) teaches that one approach to the prevention or of serious bacterial infection involve bacterial adherence [see abstract]. The receptors on cell membranes for gram-negative bacteria are composed of carbohydrates. In some instances, the receptor is such that mannose alone of many sugars tested is capable of blocking the binding of the organism to host cells. In other cases, the receptors are composed of more complex carbohydrate polymers. The receptor for the gram-positive organism *S. pyogenes* resides in an albumin-like membrane protein or glycoprotein [page 332, second column, second paragraph]. Specific molecules of recognition exist between various species of pathogenic bacteria and the tissues of the host [page 333, Bacterial Adherence vs. Bacterial Infectivity]. Beachey teaches specific adhesion and receptors of various bacteria. The receptors are different for different bacteria, and for some bacteria, are not known [page 334, Table 2]. Beachey teaches the relationship between adherence of bacteria in vitro and bacterial infectivity in vivo. *Salmonella* had moderate infectivity although poor adherence [page 335, Table 3].

Merck Manuals Online (Bacterial Infections – Introduction) teaches that there are many types of bacterial infections which require different treatments [entire document].

The term "bacterial infection" is very broad and encompasses such diseases as anthrax, tetanus, plague, typhoid fever, gas gangrene, smallpox, necrotizing fasciitis, and many others.

The term “infection,” given its broadest reasonable interpretation, is interpreted as invasion of the body by pathogenic microorganisms. While the specification is enabling for treatment of conditions caused by infection and for inhibiting the growth of pathogenic microorganisms in the body, it is not enabling for the prevention of invasion by microorganisms.

Mayoclinic.com (Bacterial infection vs. viral infection: What’s the difference?) teaches that bacteria and viruses are different and that medications that are effective against one aren't effective against the other.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for the treatment of *E. coli* and *zHelicobacter* infections.

However, the specification does not provide guidance for the prevention of gastrointestinal infections or the treatment of infections caused by other than *E. coli* and *zHelicobacter* infections. For example, no guidance is given as to the amounts, combinations, or mode of administration of oligosaccharides which would be effective for the treatment of a viral gastrointestinal infection or for other bacterial infections. As taught by Beachey, binding is specific to each microorganism, the receptors for some

bacteria are not known, and some bacteria do not even have receptors composed of carbohydrates.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the breadth of the claims, the recitation of "prophylactically effective," the broadest reasonable interpretation of infection, and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Response to Arguments

Applicant argues that carbohydrate mediated binding is a key pathogenic mechanism in microbial infections and thus prevention of gastrointestinal infection is enabled. This argument is not persuasive because “prevention” is given its broadest reasonable interpretation, which is absolute prevention. Oligosaccharides may inhibit adhesion of a bacterium but could not be expected to prevent adhesion of every microorganism, absolutely.

Applicant argues that adhesion of a pathogen to a host tissue is required for infection. As taught by Beachey, microorganisms having low adherence can still cause infection.

Applicant argues that Prieto teaches that oligosaccharides protect infants from bacterial infections. Protection is not absolute prevention. As taught by Pickering (see

102 rejection below), breastfed infants have less occurrences of diarrhea, not zero occurrences.

Applicant argues that numerous patents related to other pathogen receptor types/infections use the term "prevention." Applicant arguments are not found convincing since each application for patent is examined on its own merits, and patents are property and not available as precedent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 92, 94-97, 105, and 106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 92 (and dependent claims) recites the limitation "a therapeutical composition containing purified fraction(s) of at least two compounds." This recitation is indefinite because "containing" is open language, which permits the inclusion of elements other than purified fraction(s) in the composition. The specification defines "purified fraction" as a purified or isolated oligosaccharide fraction from natural or synthetic sources. However, the recitation of "purified" to describe a fraction which can be accompanied by any number of other elements, which could be considered impurities, is contradictory. It is unclear what is meant to be excluded by the claim.

Response to Arguments

Applicant argues that therapeutic compositions may include materials other than the purified or isolated oligosaccharide fractions and thus the claim is not indefinite. Applicant's argument is not persuasive because it is unclear what is meant to be excluded by "purified."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 92, 94-97, 105, and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by Pickering et al. (Infection 21 (1993) No. 6, pages 355-357, of record).

Pickering et al. teach that breastfed infants residing in areas having poor sanitation, despite the presence of fecal organisms in colostrum of the mothers, have less occurrences of diarrhea than urban infants who were not breastfed [page 355, Epidemiologic Studies of Breastfeeding]. Human milk protects against enteropathogens such as *Vibro cholerae*, *Campylobacter jijuni*, enteropathogenic and enterotoxigenic *Escherichia coli*, Shigella, *Giardia lambia*, and rotavirus [page 355, Table 1].

Human milk is a composition which contains both LnNT and Neu5Acα3Galβ4Glc, Applicants' elected species. Human milk is a therapeutic composition, as taught by Pickering et al. Given the broadest reasonable interpretation of the claims, as discussed in the previous rejection, the free LnNT and Neu5Acα3Galβ4Glc in human

milk can be considered purified fractions within the milk composition. Infants living in areas of poor sanitation and ingesting milk contaminated with fecal organisms are considered subjects in need of treatment for bacterial infection. Thus, the claims are anticipated by Pickering et al.

Response to Arguments

Applicant argues that human milk contains numerous active components and that Pickering et al. do not refer to the specific saccharides. Applicant admits that human milk contains LnNT and Neu5Acα3Galβ4Glc. Pickering teaches administration of human milk. Thus, Pickering teaches administration of a composition containing LnNT and Neu5Acα3Galβ4Glc and the claims are anticipated.

Applicant argues that LnNT and Neu5Acα3Galβ4Glc do not occur as purified fractions within the milk composition. As discussed above, it is unclear what is meant to be excluded by "purified." The specification, page 92, defines "purified fraction" as purified or isolated oligosaccharide fraction from natural or synthetic sources. However, the use of "comprising" permits any other element to be present in the composition, without limit. The specification, page 96, states that the nutritional composition could be part of an infant formula or food product, which is certain to contain other compounds. The claims do not require the exclusion of any particular element and do not require specific amounts or proportions of oligosaccharides which might distinguish the composition from human milk. Thus, Applicant's argument is not persuasive.

Conclusion

Applicant's amendment and submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on June 27, 2008 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Tuesday - Friday, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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